

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION**

GENBIOPRO, INC.,

Plaintiff,

v.

**MARK A. SORSAIA, in his official capacity as
Prosecuting Attorney of Putnam County AND
PATRICK MORRISEY, in his official capacity
as Attorney General of West Virginia,**

Defendants.

**Civil Action No.: 3:23-cv-00058
(Hon. Robert C. Chambers)**

**MOTION OF FOOD AND DRUG LAW AND
HEALTH LAW SCHOLARS FOR LEAVE TO FILE
AN AMICUS CURIAE BRIEF IN SUPPORT OF PLAINTIFF'S
OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS**

Under Fed. R. Civ. P. 7, the amici food and drug law and health law scholars respectfully move for leave to file a brief as amici curiae in the above-captioned case in support of Plaintiff's opposition to Defendants' motions to dismiss. Plaintiff and Defendant Morrissey consented to the filing of this amicus brief; at the time of filing, Defendant Sorsaia had not responded to amici's request for their position on the filing of the brief.

IDENTITY AND INTERESTS OF AMICI CURIAE

The amici are eight legal scholars from seven academic institutions across the United States, specializing in U.S. food and drug law, health law, bioethics, and constitutional law.¹ Specifically, amici include:

¹ The views in the amicus curiae brief are those of the amici in their individual capacities and do not necessarily represent the views of their respective institutions.

- **David S. Cohen, JD:** David S. Cohen is a Professor of Law at Drexel University Thomas R. Kline School of Law. His scholarship focuses on the intersection of constitutional law and gender, with a particular emphasis on abortion. Prior to teaching, Professor Cohen was a staff attorney at the Women's Law Project.
- **Greer Donley, JD:** Greer Donley is the John E. Murray Faculty Scholar and Associate Professor of Law at the University of Pittsburgh Law School. Her research focuses on reproductive rights, FDA law, and health law.
- **Lewis A. Grossman, JD, PhD:** Lewis Grossman is a Professor of Law at the American University Washington College of Law. He teaches and writes in the areas of food and drug law, health law, American legal history, and civil procedure. He is the co-author of *Food and Drug Law: Cases and Materials* (5th Edition 2022) and has served as a member or legal consultant on four committees of the Health and Medicine Division (formerly the Institute of Medicine) of the National Academies of Sciences, Engineering, and Medicine.
- **Rachel Rebouché, JD, LLM:** Rachel Rebouché is the Dean of the Temple University Beasley School of Law and the James E. Beasley Professor of Law. Professor Rebouché is a leading scholar in reproductive health law and family law. She has served as a co-investigator on two grant-funded research projects related to reproductive health, one housed at the Emory University Rollins School of Public Health and another funded by the World Health Organization.
- **Patricia J. Zettler, JD:** Patricia J. Zettler is an Associate Professor of Law at the Ohio State University Moritz College of Law and a member of Ohio State's Drug Enforcement and Policy Center and its Comprehensive Cancer Center. Her research focuses on FDA law and policy, and she is a co-author of *Food and Drug Law: Cases and Materials* (5th Edition 2022). Before her academic career, she served as an associate chief counsel in FDA's Office of the Chief Counsel.
- **I. Glenn Cohen, JD:** I. Glenn Cohen is a professor at Harvard Law School. His research focuses on bioethics and health law, with current projects in FDA law, abortion, and reproductive technologies.
- **Peter Barton Hutt, LLM, LLB:** Peter Barton Hutt is a Senior Counsel at Covington & Burling LLP specializing in Food and Drug Law and a former Chief Counsel of FDA. He is the lead co-author of *Food and Drug Law: Cases and Materials* (5th Edition 2022) and has taught a full course on the subject at Harvard Law School for thirty consecutive years.
- **Allison M. Whelan, JD, MA:** Allison M. Whelan is an Assistant Professor of Law at Georgia State University College of Law where her scholarship and teaching focuses on FDA law, reproductive justice, administrative law, and bioethics. Prior to her academic career, she practiced food and drug law at a large law firm.

All amici are independent of the parties to this action.

ARGUMENT

Courts have broad discretion to grant a motion for leave to file an amicus brief. *Ohio Valley Env't Coal., Inc. v. McCarthy*, 313 F.R.D. 10, 32 (S.D.W. Va. 2015); *United States v. Bayer Cropscience LP*, No. 2:15-CV-13331, 2018 WL 3553413, at *10 (S.D.W. Va. July 24, 2018); *see also Tafas v. Dudas*, 511 F. Supp. 2d 652, 659 (E.D. Va. 2007). When deciding, courts consider whether the amicus brief will “help sharpen the issues for review.” *Bayer Cropscience LP*, 2018 WL 3553413, at *10; *see also Ohio Valley Env't Coal., Inc.*, 313 F.R.D. at 32 (allowing the filing of an amicus brief because the perspective of the *amici* “would be useful to the existing parties and this Court”).

Amici’s brief offers useful information to the Court. Amici seek to assist the Court by offering their expertise on the U.S. Food and Drug Administration (FDA or the Agency) and its regulation of medication abortion. In particular, amici’s brief provides additional context on FDA’s broad authority to approve and regulate new drugs for use in the United States, and how the Agency has leveraged this authority to regulate mifepristone’s prescribing, distribution, and dispensing since its approval in 2000. The additional information provided in amici’s brief will be useful to the Court as it considers the issues raised in this dispute.

Neither amici nor counsel received any monetary contributions to fund the preparation or submission of this brief and no party’s counsel authored this brief in whole or in part.

For the foregoing reasons, the above-listed amici respectfully request this Court’s leave to submit the attached amicus curiae brief for filing.

Dated: March 20, 2023

Respectfully submitted,

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Counsel for Food and Drug Law and Health Law Scholars
* Statement of Visiting Attorney filed

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Motion of Food and Drug Law and Health Law Scholars for Leave to File an Amicus Curiae Brief in Support of Plaintiff was served on this 20th day of March, 2023 on all counsel of record via CM/ECF and filed consistent with LR Civ P 5.1(c).

/s/ Russell D. Jessee

Russell D. Jessee